



Implementation of Dengue Vaccine in Puerto Rico

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Population under VFC

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AWARDEE POPULATION ESTIMATES

TABLE I - TOTAL POPULATION ESTIMATE FOR FY2020

Population Estimate

	Years of Age				Total
	0-1	1-2	3-6	7-18	
Awardee population estimate for FY2020	27,379	57,373	130,823	485,482	701,057
Awardee approved population estimate for FY2019	30,122	63,135	140,676	509,021	742,954

VFC ELIGIBILITY SUMMARY

TABLE II - VFC ELIGIBLE FOR FY2020

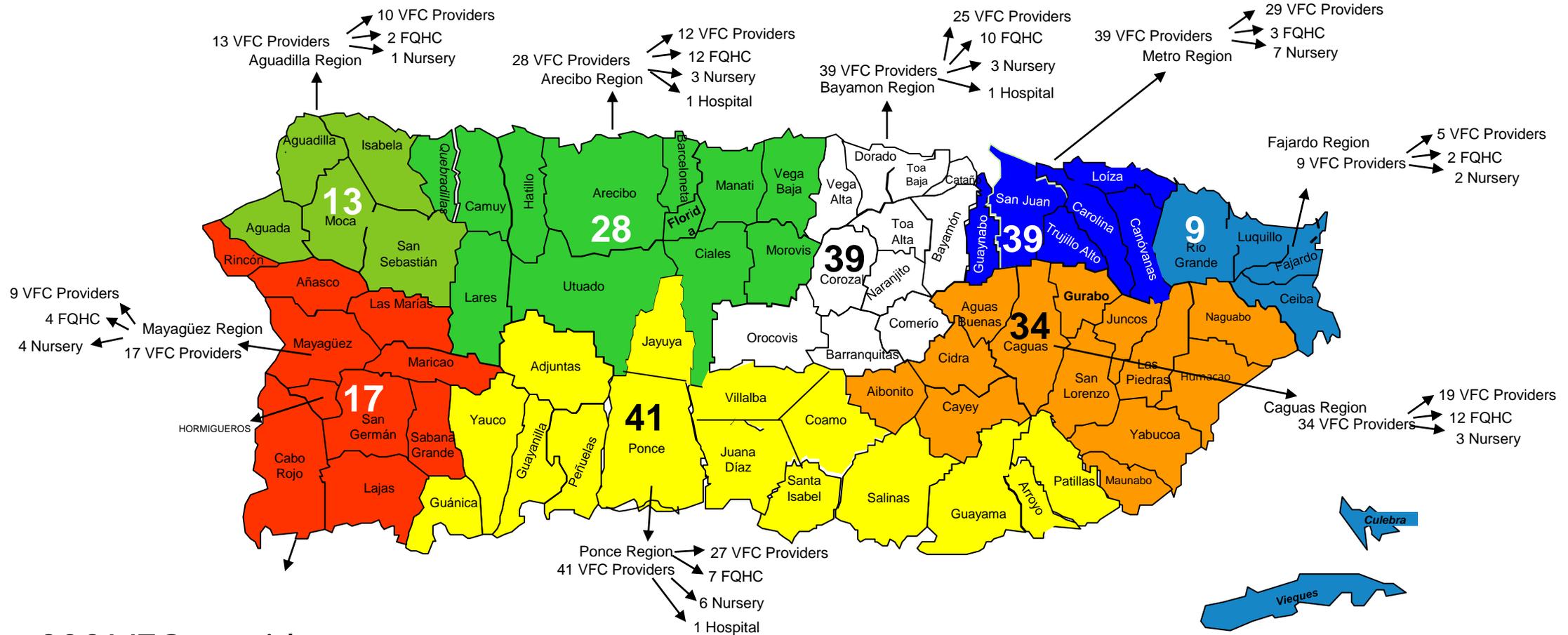
VFC Eligibility Definitions

VFC Eligibility Definitions	Years of Age				Total
	0-1	1-2	3-6	7-18	
MEDICAID ESTIMATE FOR FY2020	12,559	29,711	63,847	197,882	303,999
THE NUMBER OF AMERICAN INDIANS/ALASKA NATIVES	0	0	0	0	0
THE NUMBER OF CHILDREN WITHOUT HEALTH INSURANCE	834	1,669	2,503	20,022	25,028
FQHC/RHC	53	163	69	757	757
DELEGATED AUTHORITY (DA)	0	0	0	0	0
DA DATA SOURCE COMMENTS	n/a				
SUB-TOTAL VFC ELIGIBLE	13,446	31,543	66,419	218,376	329,784
NON-VFC ELIGIBLE	13,933	25,830	64,404	267,106	371,273

Children 7-18 years
VFC 45%
Medicaid 41%
Uninsured 4%
Private 55%



Regions and VFC providers



- 209 VFC providers
- 296 Private providers



VFC Program

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A child is eligible for the VFC Program if he or she is younger than 19 years of age and is one of the following:

- ✓ Medicaid eligible
- ✓ Un-insured
- ✓ Under-insured
- ✓ American Indian or Alaska native

Uninsured and underinsured children are eligible to receive only at Federally Qualified Health Centers (FQHC) or Rural Health Clinics (RHC). An FQHC is a type of provider that meets certain criteria under Medicaid programs.

PRDoH Immunization Program

Mission and Vision

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Mission

To prevent the development of vaccine preventable diseases through strategic implementation and intervention facilitating services in accordance with the vaccine schedule for children, adolescents and adults of Puerto Rico.

Vision

To maintain a protected population against vaccine preventable diseases thus reducing outbreaks, hospitalizations and deaths.

PRDoH Immunization Program

What we do?

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- Recommend immunization public policy
- Guarantee immunization quality services
- Supply vaccines funded by the federal government to vaccine providers for Medicaid
- Audit vaccine management, storage, handling and administration
- Promote and educate parents on importance and security of vaccines
- Implement the PR Immunization Law (#25)
- Do not offer direct patient care services except during public health emergencies

Enacted on September 1983

For all day care centers,
schools and universities

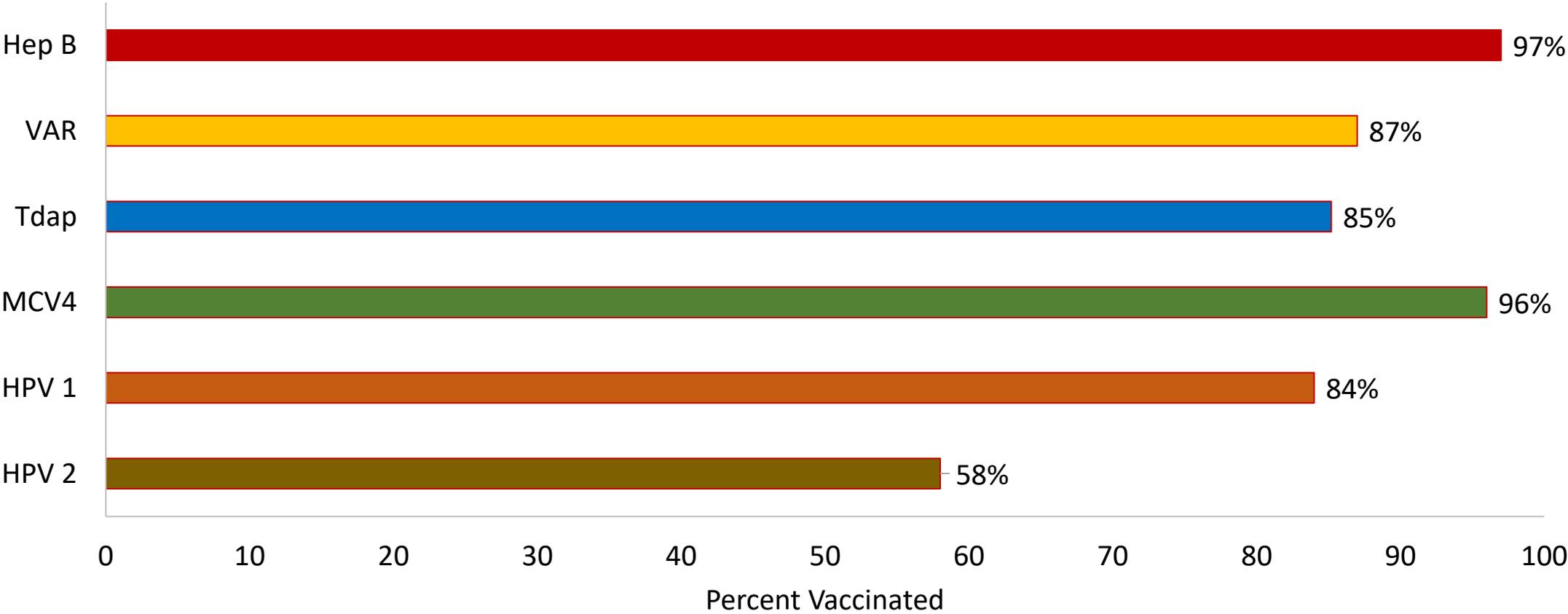
Puerto Rico Immunization Law

<https://adobe.ly/31wTyVv>

Allow for medical and religious
exemptions only

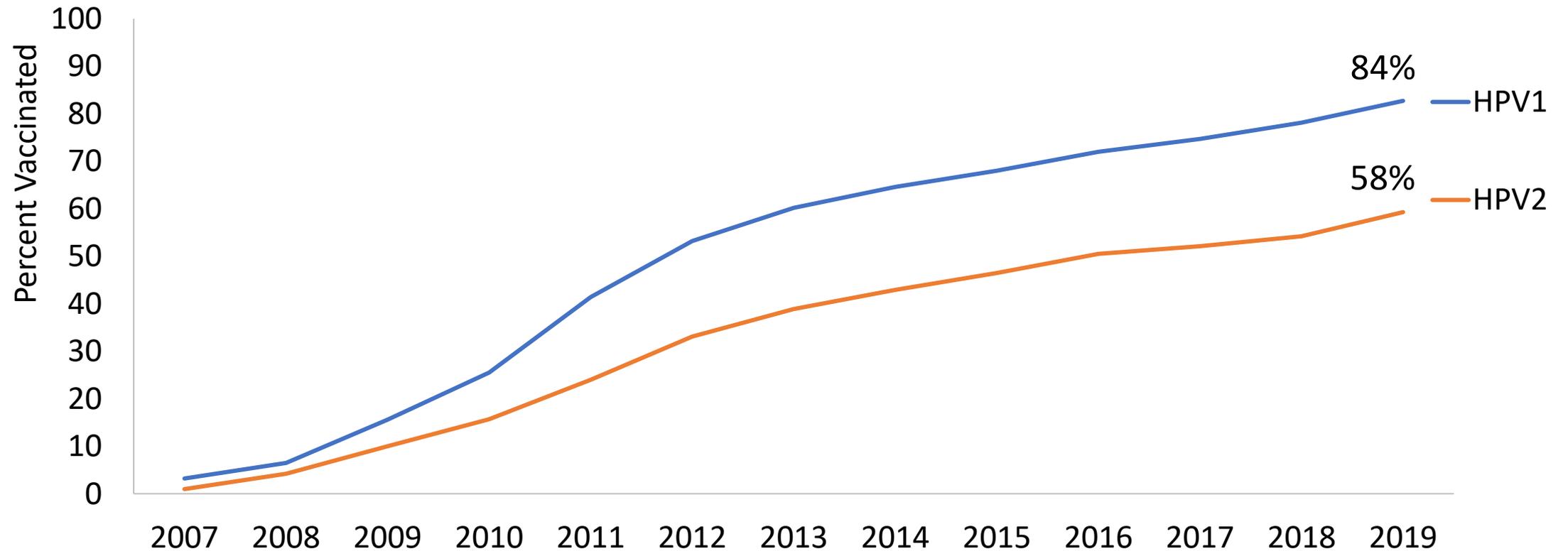
Secretary of Health determines all
immunization school requirements
adhering to ACIP
recommendations

Estimated vaccination coverage adolescents 13-17 years, Puerto Rico, 2019



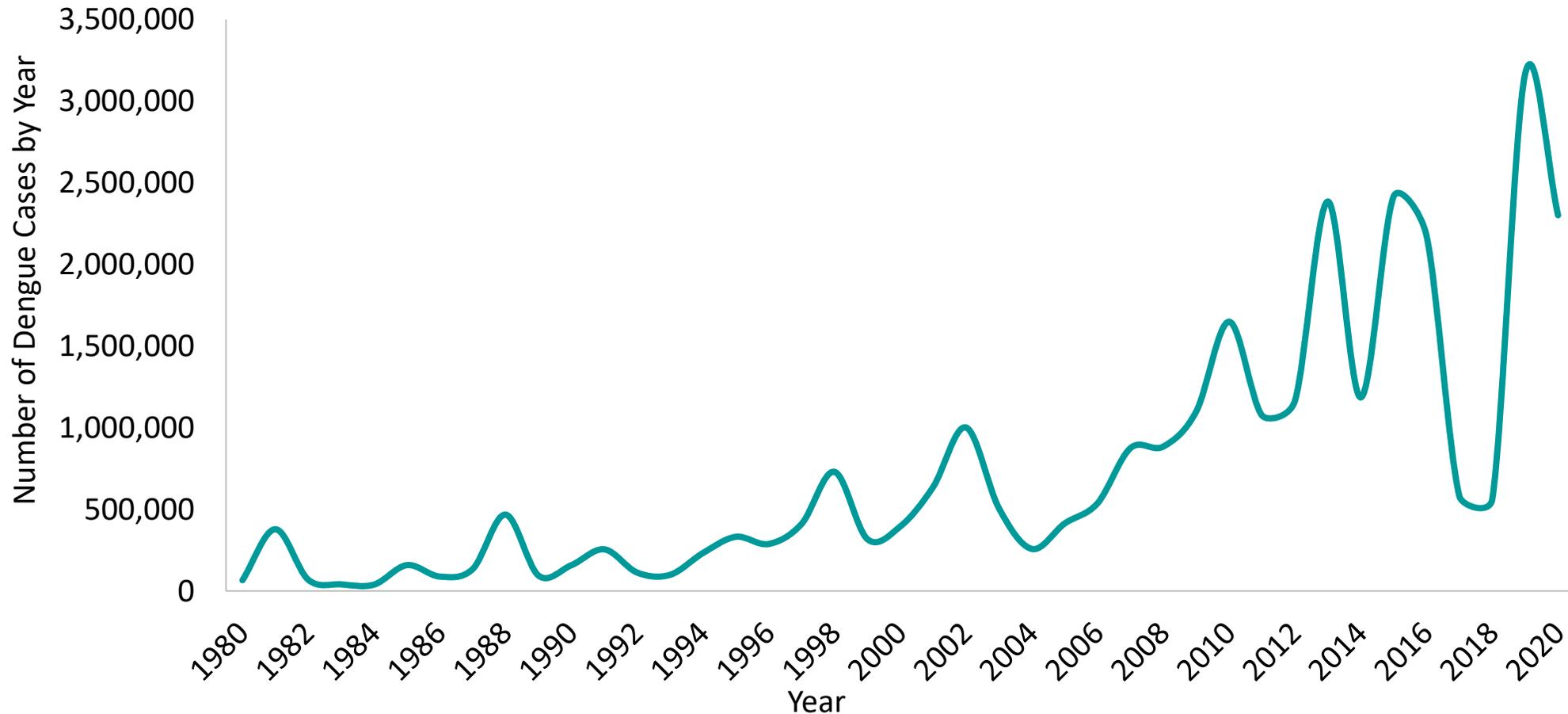
Fuente: Registro de Inmunización de PR (PRIR), Programa de Vacunación, Departamento de Salud de PR

Estimated coverage HPV vaccine adolescents 13-17 years, Puerto Rico, 2007-2019



Dengue vaccine implementation in Puerto Rico

Reported dengue cases in the Americas by year, 1980–2020



Source: Pan American Health Organization, PLISA Health Information Platform

Suspect Dengue in Puerto Rico, 1986-2013

Dengue epidemics
occur every 3-5 years
in Puerto Rico

reported cases (weekly)

1000
600
200
0
1

HEALTHCARE & PHARMA MAY 12, 2020 / 9:05 AM / UPDATED A YEAR AGO

'Dengue kills too' - Latin America faces two epidemics at once

By Oliver Griffin

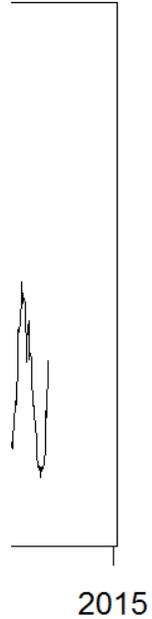
5 MIN READ



BOGOTA (Reuters) - As the coronavirus kills thousands and dominates government attention across Latin America, another deadly viral infection is quietly stalking the region.

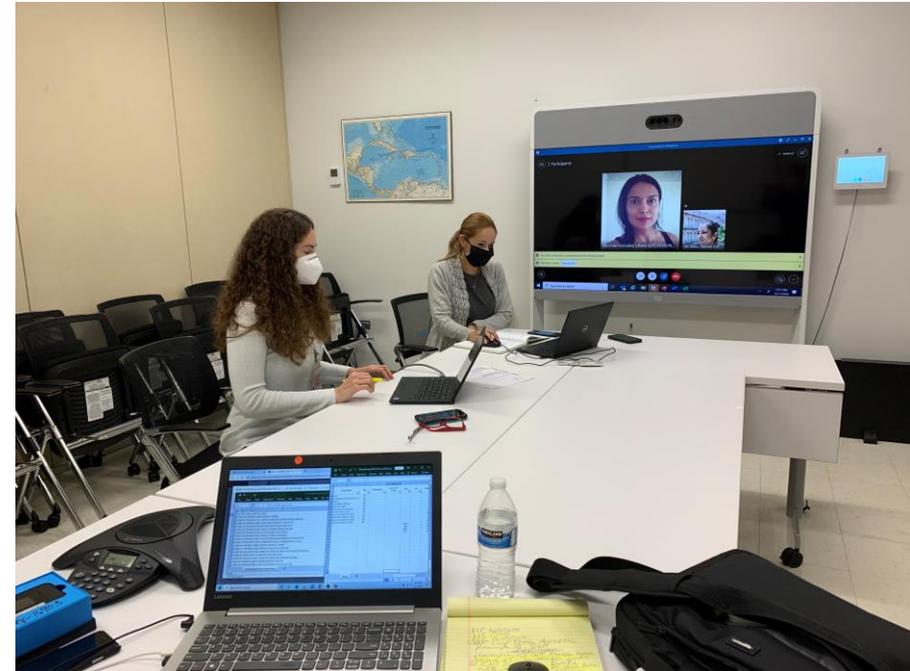


FILE PHOTO: Aedes aegypti mosquitoes are seen inside Oxitec laboratory in Campinas, Brazil, February 2, 2016. REUTERS/Paulo Whitaker



Education of providers and parents

- Assemble education materials for physicians
 - Training sessions
 - Pediatric associations
 - College of physicians
 - College of nurses
- Educational material for parents
 - Post materials for doctor's office and vaccination clinics
- Media campaign to inform the public



Who will pay?

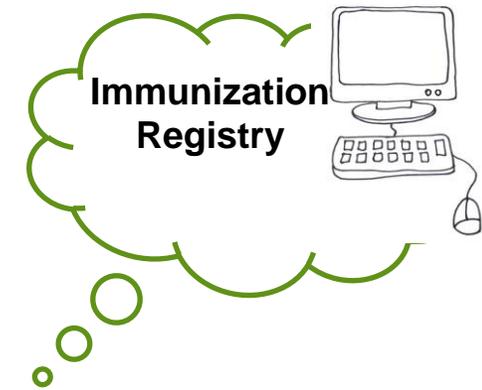
- Vaccine costs covered by VFC and insurance
- Medicaid will cover the cost of the test for Medicaid eligible
- Insurance will cover the cost of the test for those with private insurance
- For those uninsured or underinsured sources of funding will be identified

Pre-vaccination screening serologic testing

- Puerto Rico laboratories have experience using non-FDA approved tests under Clinical Laboratory Improvement Amendments (CLIA)
- The PR health department will consider providing specific guidance on the test approved locally for pre-vaccination
- After FDA approval pediatricians can apply for permission to run the test in their clinics
- Standing orders for dengue IgG pre-vaccination screening tests in immunization clinics will be considered
- Testing orders and results can be received online

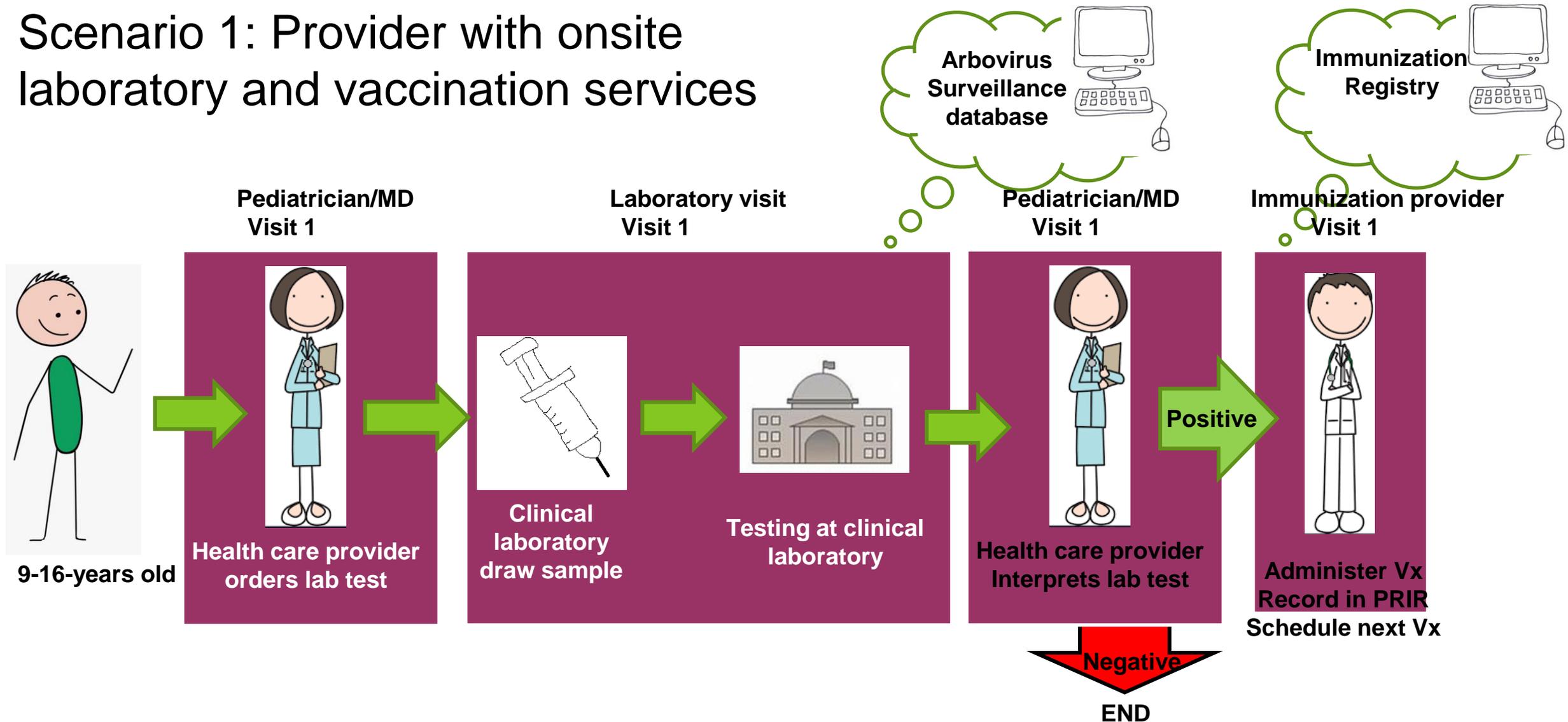
Arbovirus surveillance system

- Dengue testing is currently centralized
- Arbovirus surveillance system will be updated to receive reports from private laboratories
- Test results will be linked to data from the immunization registry



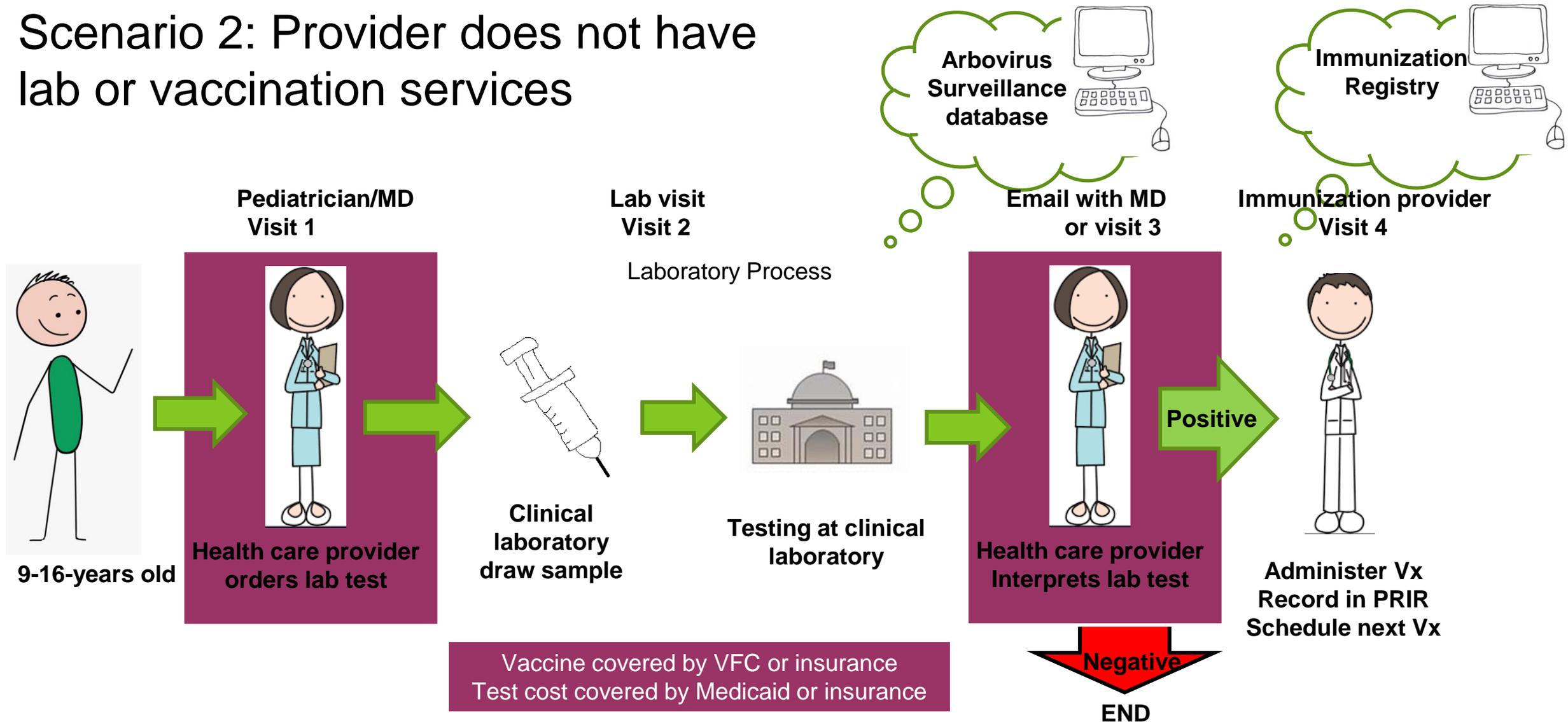
Logistics of dengue vaccination in Puerto Rico

Scenario 1: Provider with onsite laboratory and vaccination services



Logistics of dengue vaccination in Puerto Rico

Scenario 2: Provider does not have lab or vaccination services





Pediatrician



Laboratory



Vaccination



**FQHC and CDT have all services
Phased-in implementation can
start at these sites**

The Vaccine Life Cycle

safety at every phase

GUIDE

ACIP

ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES

BLA

BIOLOGICS LICENSE APPLICATION

CDC

CENTERS FOR DISEASE CONTROL AND PREVENTION

FDA

FOOD AND DRUG ADMINISTRATION

IND

INVESTIGATIONAL NEW DRUG APPLICATION

VACCINE

DEVELOPMENT

safety is a priority during vaccine development + approval

safety continues with CDC + FDA safety monitoring

PHASE 1 safety
PHASE 2 effectiveness
PHASE 3 safety + effectiveness

PHASE 4 safety monitoring for serious, unexpected adverse events

BASIC RESEARCH
DISCOVERY
PRE-CLINICAL STUDIES

CLINICAL STUDIES / TRIALS

FDA REVIEW

ACIP REVIEW

POST-APPROVAL MONITORING + RESEARCH

IND SUBMITTED

BLA SUBMITTED

FDA APPROVAL OF 1 NEW VACCINE

ACIP RECOMMENDATION

How will we monitor for vaccine safety events post-approval?

Detection through VAERS

- Puerto Rico has an appointed and experienced VAERS coordinator
- Events regularly reported to VAERS
 - 817 events reported in 2021 as of 5/22 (CDC WONDER)
- Likely to detect events immediately after vaccination

VAERS

Vaccine Adverse Event Reporting System
www.vaers.hhs.gov

Long term vaccine safety

- Hospitalizations and severe dengue
- Will likely happen several years after vaccination
- Reported through the existing passive dengue surveillance system

DENV case surveillance in Puerto Rico

- All DENV testing centralized at Puerto Rico Department of Health Laboratory
 - Biological and Chemical Emergency Laboratory (BCEL)
- Specimens submitted with case investigation form
- All cases captured in Arboviral Database
- Under-reporting exists, ratio of 1 reported for every 5–9 hospitalized (Shankar, 2018)

FORMULARIO DE INVESTIGACIÓN DE CASO DE ARBOVIRUS
 Laboratorio de Salud Pública de Puerto Rico
 Edificio A – Segundo Piso, Área de Centro Médico
 Tel. (787)765-2929 ext. 3728, Fax (787) 274-5710

GOBIERNO DE PUERTO RICO
 Departamento de Salud

Favor de leer y completar TODAS las secciones. Vea instrucciones en el lado dorsal.

1. Datos del paciente La hospitalizaron por esta enfermedad: No Sí → Nombre del hospital: _____ Número de expediente: _____

Nombre del paciente: Apellido paterno _____ Apellido materno _____ Nombre _____ Segunda nombre/Inicial _____
 Falleció: Sí No No sabe

Si el paciente es un menor, nombre del padre o encargado: Apellido paterno _____ Apellido materno _____ Nombre _____ Segunda nombre/Inicial _____
 Cambios de estatus mental: Sí No No sabe

2. Dirección residencial (física) completa del paciente **5. Información de contacto del médico**

Urbanización/Sector/Edificio: _____ Médico que ordenó prueba - Nombre: _____
 National Provider Identifier (NPI): _____
 Número: _____ Calle: _____ Tel: _____ Fax: _____ Email: _____
 Municipio: _____ Código postal: _____ Dirección postal: Número: _____ Calle: _____
 Tel: _____ Otro Tel: _____ Municipio: _____ Código postal: _____
 Vive cerca de: _____ Hospital/Clinica/Laboratorio: _____ Especialidad: _____
 Nombre y dirección del trabajo: _____ Médico primario - Nombre: _____
 National Provider Identifier (NPI): _____
 Tel: _____ Fax: _____ Email: _____
 Dirección postal: Número: _____ Calle: _____
 Municipio: _____ Código postal: _____
 Hospital/Clinica/Laboratorio: _____ Especialidad: _____

3. Información demográfica del paciente: **6. ¿Quién llenó este formulario?**

Fecha de nacimiento: Edad: _____ mes Sexo: M F NS
 o edad: _____ años Embarazada: Sí No NS
 Día Mes Año Semanas de gestación: _____
 Fecha Estimada de Parto Día /Mes /Año

Nombre _____ Relación con paciente: _____
 Tel: _____ Fax: _____ Email: _____

4. Estatus de síntomas e inicio/Fecha de la muestra **7. Datos adicionales del paciente**

¿Paciente sintomático? Sí No Día Mes Año
 Si está sintomático, fecha de primer(os) síntoma(s) _____ Fecha toma de muestra _____
 Muestra de suero _____
 Otra muestra (especifique tipo: _____) _____
 Otra muestra(especifique tipo: _____) _____
 Otra muestra(especifique tipo: _____) _____

País de nacimiento _____
 ¿Durante los 14 días antes de enfermarse, viajó a otro país, o municipio?
 Sí, otro país Sí, otro municipio No No sabe
 ¿A donde viajó? _____

8. Descripción de signos y síntomas que tiene el paciente al momento de completar este formulario

	Sí	No	No sabe	Síntomas	Sí	No	No sabe	Señales de alerta	Sí	No	No sabe
Fiebre durante 2-7 días.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Pulso acelerado y débil.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Vértigos persistentes.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Fiebre ahora (>38°C).....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Palidez o piel fría.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Dolor abdominal/sensibilidad.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Plaquetas ≤100,000/mm ³	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Escalofríos.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Sangrado de las mucosas.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Conteo de plaquetas: _____				Sarpullido.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Letargia/intranquilidad.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Alguna manifestación hemorrágica:				Dolor de cabeza.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Agrandamiento del hígado >2cm.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Petequias.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Dolor en los ojos.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Efusión pleural o abdominal.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Equimosis o cardenales.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Dolor en el codo(músculo/hueso).....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Síntomas adicionales			
Vómitos con sangre.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Dolor de coyunturas.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Diarrea.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Sangre en la excreta.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Anorexia.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Tos.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Hemorragia nasal.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Encefalitis/meningitis.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Conjuntivitis.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Hemorragia en las encías.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Infante (solamente)				Congestión nasal.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Sangre en la orina.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Microcefalia.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Dolor de garganta.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Hemorragia vaginal.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Calcificaciones intracraneales.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Ictericia.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Urticaria positiva.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Otro defecto congénito.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Convulsión o coma.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(sobre 5 RBC/hpl o positivo para sangre)				Especifique.....				Núuseas y vómitos (ocasional).....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Prueba de Torniquete <input type="checkbox"/> Pos <input type="checkbox"/> Neg <input type="checkbox"/> No se hizo				Madre con resultado de Zika positivo o indeterminado.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Artritis (coyunturas hinchadas).....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

9. SOLAMENTE PARA USO DEL LABORATORIO DE SALUD PÚBLICA DE PUERTO RICO

Número de Caso	Especimen #	Días después 1er síntoma	Tipo	Fecha recibida	Especimen #	Días después 1er síntoma	Tipo	Fecha recibida
_____	_____	_____	_____	____/____/____	_____	_____	_____	____/____/____
SAN ID _____	GCODE _____	\$1 _____			\$3 _____			
		\$2 _____			\$4 _____			

FIDOH REV. 2/2016

Enhancing surveillance for dengue cases after vaccination

- Conduct outreach to hospitals to educate about the dengue vaccine
 - Retrain doctors on clinical suspicion of dengue
 - Streamline and reinforce reporting of hospitalizations for suspected dengue cases
 - Consider enhanced surveillance at children's hospitals
- 

Ascertaining vaccination information for hospitalized cases

- Add dengue vaccine history to arboviral case investigation form
- Confirm status with vaccine registry
- Monitor reported numbers of hospitalizations among vaccinated children to identify potential safety signals

Summary

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- PRDoH adopts ACIP recommendations for local vaccine schedule- reviewed annually
- Immunization registry reporting is mandatory by administrative order
- Population 9-10 years old receive limited vaccines as no routine vaccines recommended
- Dengue testing can be incorporated to annual wellness visit
- About 25% of VFC providers have lab capability in house (FQHCs & CDTs), can start pilot dengue vaccination at these sites
- Vaccine series completion in age cohort is lower for 2nd and 3rd dose

Summary

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- VAERS in place to detect adverse events short-term after vaccination
- Existing DENV surveillance system can capture cases years after vaccination
 - Need to prepare and strengthen infrastructure
- Can monitor overall numbers and use modeling to assess expected numbers



Questions?